UNITED STATES DISTRICT COURT

for the

_____ District of _____

Janell René Butler

Plaintiff(s)

(Write the full name of each plaintiff who is filing this complaint. If the names of all the plaintiffs cannot fit in the space above, please write "see attached" in the space and attach an additional page with the full list of names.)

-v-

Oregon Health & Science University, et al

Defendant(s)

(Write the full name of each defendant who is being sued. If the names of all the defendants cannot fit in the space above, please write "see attached" in the space and attach an additional page with the full list of names.)

Case No. 3:17-CV-00135-HZ

(to be filled in by the Clerk's Office)

Jury Trial: *(check one)* ☐ Yes ☐ No

AMENDED

COMPLAINT FOR A CIVIL CASE

I. The Parties to This Complaint

A. The Plaintiff(s)

Provide the information below for each plaintiff named in the complaint. Attach additional pages if needed.

Name	Janell René Butler
Street Address	P.O Box 151
City and County	Cornelius Wash CO
State and Zip Code	OR 97113
Telephone Number	971-340-5854
E-mail Address	

B. The Defendant(s)

Provide the information below for each defendant named in the complaint, whether the defendant is an individual, a government agency, an organization, or a corporation. For an individual defendant, include the person's job or title *(if known)*. Attach additional pages if needed.

Defendant No. 1

Name: Kathryn Schabel
Job or Title *(if known)*: Orthopedic Surgeon
Street Address: 3181 SW Sam Jackson Park Road
City and County: Portland Multnomah Co
State and Zip Code: OR 97239
Telephone Number: 503-494-6288
E-mail Address *(if known)*:

Defendant No. 2

Name:
Job or Title *(if known)*:
Street Address:
City and County:
State and Zip Code:
Telephone Number:
E-mail Address *(if known)*:

Defendant No. 3

Name:
Job or Title *(if known)*:
Street Address:
City and County:
State and Zip Code:
Telephone Number:
E-mail Address *(if known)*:

Defendant No. 4

Name:
Job or Title *(if known)*:
Street Address:
City and County:
State and Zip Code:
Telephone Number:
E-mail Address *(if known)*:

II. Basis for Jurisdiction

Federal courts are courts of limited jurisdiction (limited power). Generally, only two types of cases can be heard in federal court: cases involving a federal question and cases involving diversity of citizenship of the parties. Under 28 U.S.C. § 1331, a case arising under the United States Constitution or federal laws or treaties is a federal question case. Under 28 U.S.C. § 1332, a case in which a citizen of one State sues a citizen of another State or nation and the amount at stake is more than $75,000 is a diversity of citizenship case. In a diversity of citizenship case, no defendant may be a citizen of the same State as any plaintiff.

What is the basis for federal court jurisdiction? *(check all that apply)*

☒ Federal question ☐ Diversity of citizenship

Fill out the paragraphs in this section that apply to this case.

A. If the Basis for Jurisdiction Is a Federal Question

List the specific federal statutes, federal treaties, and/or provisions of the United States Constitution that are at issue in this case.

45 CFR Part 690 Subpart A, The Common Rule For The Protection of Human Subjects Federal Policy Section §.116(a)(1-8) General Requirements For Informed Consent

B. If the Basis for Jurisdiction Is Diversity of Citizenship

1. The Plaintiff(s)

a. If the plaintiff is an individual

The plaintiff, *(name)* _____, is a citizen of the State of *(name)* _____.

b. If the plaintiff is a corporation

The plaintiff, *(name)* _____, is incorporated under the laws of the State of *(name)* _____, and has its principal place of business in the State of *(name)* _____.

(If more than one plaintiff is named in the complaint, attach an additional page providing the same information for each additional plaintiff.)

2. The Defendant(s)

a. If the defendant is an individual

The defendant, *(name)* _____, is a citizen of the State of *(name)* _____. Or is a citizen of *(foreign nation)* _____.

b. If the defendant is a corporation

The defendant, *(name)* Oregon Health & Science University, is incorporated under the laws of the State of *(name)* Oregon, and has its principal place of business in the State of *(name)* Oregon.

Or is incorporated under the laws of *(foreign nation)* _____,

and has its principal place of business in *(name)* Portland.

(If more than one defendant is named in the complaint, attach an additional page providing the same information for each additional defendant.)

3. The Amount in Controversy

The amount in controversy-the amount the plaintiff claims the defendant owes or the amount at stake-is more than $75,000, not counting interest and costs of court, because *(explain)*:

III. Statement of Claim

Write a short and plain statement of the claim. Do not make legal arguments. State as briefly as possible the facts showing that each plaintiff is entitled to the damages or other relief sought. State how each defendant was involved and what each defendant did that caused the plaintiff harm or violated the plaintiff's rights, including the dates and places of that involvement or conduct. If more than one claim is asserted, number each claim and write a short and plain statement of each claim in a separate paragraph. Attach additional pages if needed.

IV. Relief

State briefly and precisely what damages or other relief the plaintiff asks the court to order. Do not make legal arguments. Include any basis for claiming that the wrongs alleged are continuing at the present time. Include the amounts of any actual damages claimed for the acts alleged and the basis for these amounts. Include any punitive or exemplary damages claimed, the amounts, and the reasons you claim you are entitled to actual or punitive money damages.

V. Certification and Closing

Under Federal Rule of Civil Procedure 11, by signing below, I certify to the best of my knowledge, information, and belief that this complaint: (1) is not being presented for an improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of litigation; (2) is supported by existing law or by a nonfrivolous argument for extending, modifying, or reversing existing law; (3) the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery; and (4) the complaint otherwise complies with the requirements of Rule 11.

A. For Parties Without an Attorney

I agree to provide the Clerk's Office with any changes to my address where case-related papers may be served. I understand that my failure to keep a current address on file with the Clerk's Office may result in the dismissal of my case.

Date of signing: 3-17-17

Signature of Plaintiff Janell Rene Butler

Printed Name of Plaintiff JANELL RENE BUTLER

B. For Attorneys

Date of signing: _____

Signature of Attorney _____

Printed Name of Attorney _____

Bar Number _____

Name of Law Firm _____

Street Address _____

State and Zip Code _____

Telephone Number _____

E-mail Address _____

Your Honorable Judge Hernandez;

When I went in for a rt total knee replacement I did not consent to the experimental wiring procedure I gave you articles on. Nor I would I have consented to the pain, misery and all of the problems it has caused throughout my entire body.

One of my major problems with this is that a doctor/surgeon who took an oath to guide, consult, and heal would do the exact opposite in this case.

On July 28, 2014 I thought I was going to have a whole new way of life without so much pain and with my new knee have a new way of life in general with my overall health. Many things that I thought were going to come out better ended up worse.

I kept telling Dr Kathryn Schabel not to long after my surgery about the migraine headaches, my left hip and leg speaking of pain and numbness, as well as chronic pain all the way up and down my spine.

I have gone to OHSU neurologist and pain center about a year finally after my surgery on July 28, 2014 but not even a real assessment was ever done at either specialist.

So I attempted to ask for a second opinion with another orthopedic doctor at OREGON HEALTH AND SCIENCE UNIVERSITY and my request was denied.

This procedure has cost me not only activities that I used to do but anger and depression from chronic pain.

Dr Kathryn Schabel has crossed the line as far as wanting whats best for her patients but more importantly furthering her career.

When OHSU has done other experimental procedures and patients have suffered from it the lawsuits ranged from 3.2 million all the way up to 22 million.

This is a federal policy for protection of human subjects!! This is why it has federal jurisdiction!!

Janell Reni Fuller

Highlighted In These Pages

National Science Foundation

45 CFR Part 690: Federal Policy for the Protection of Human Subjects

(Same as 45 CFR Part 46, which pertains to HHS)

Subpart A:

THE COMMON RULE FOR THE PROTECTION OF HUMAN SUBJECTS

§. .101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in § .102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in § .102(e) must be reviewed and approved, in compliance with § .101, § .102, and § .107 through § .117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings,

involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability. or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b) (2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or

(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) public benefit or service programs;

(ii) procedures for obtaining benefits or services under those programs;

(iii) possible changes in or alternatives to those programs or procedures; or

(iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,

(i) if wholesome foods without additives are consumed or

(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Protection from Research Risks, Department of Health and Human Services (HHS), and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures. [1]

[1] Institutions with HHS-approved assurances on file will abide by provisions of Title 45 CFR Part 46 Subparts A-D. Some of the other Departments and Agencies have incorporated all provisions of Title 45 CFR Part 46 into their policies and procedures as well. However, the exemptions at 45 CFR Part 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, Subparts B and C. The exemption at 45 CFR Part 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, Subpart D, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

§ .102 Definitions.

(a) *Department or agency head* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including federal, state, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for

example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) data through intervention or interaction with the individual, or

(2) identifiable private information. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) *Certification* means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

§ .103 Assuring compliance with this policy - research conducted or supported by any federal department or agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Protection from Research Risks, HHS, and approved for federal wide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Protection from Research Risks, HHS.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the

assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency- supported or regulated research and need not be applicable to any research exempted or waived under § .101(b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with § .103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Protection from Research Risks, HHS.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into

negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under § .101(b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by § .103 of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by § .103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ .104 [Reserved]
§ .105 [Reserved]
§ .106 [Reserved]

§ .107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural back- grounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ .108 IRB functions and operations.

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in § .103(b)(4) and, to the extent required by, § .103(b)(5). (b) Except when an expedited review procedure is used (see § .110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§ .109 IRB Review of Research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § .116. The IRB may require that information, in addition to that specifically mentioned in § .116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § .117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ .110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Protection from Research Risks, National Institutes of Health, HHS, Bethesda, Maryland 20892.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in § .108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

§ .111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:
(i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
(ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § .116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § .117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ .112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ .113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the

investigator, appropriate institutional officials, and the department or agency head. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ .114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

§ .115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in § .103(b)(3).

(6) Written procedures for the IRB in the same detail as described in § .103(b)(4) and § .103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by § .116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ .116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this

section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

(i) public benefit or service programs;

(ii) procedures for obtaining benefits or services under those programs;

(iii) possible changes in or alternatives to those programs or procedures; or

(iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

§ .117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § .116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by § .116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking

the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

§___.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under § .101(b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§___.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

§ .120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a federal department or agency.

The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ .121 [Reserved]

§ .122 Use of federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ .123 Early termination of research support; evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency

head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ .124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

==========END of Subpart A==========

NSF has not adopted other subparts which HHS and other agencies have adopted:

45 CFR 46 Subpart B: Research Involving fetuses, pregnant women, and human in vitro fertilization.

45 CFR 46 Subpart C: Research Involving Prisoners

45 CFR 46 Subpart D: Research Involving Children

contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

(b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.

(2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this chapter. The process shall include procedures for the receiving of reports of such information from recipients of funds under this chapter and taking appropriate action with respect to such violations.

(July 1, 1944, ch. 373, title IV, §491, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 873.)

Results

X-RAY SPINE LUMBOSACRAL 2 VIEWS (Order 167662079)

Patient Information

Patient Name	Sex	DOB
Butler, Janell	**Female**	**7/22/1974**

Collection Information

Specimen #	Collection Date and Time
E28480	**2/16/2017 0957**

Resulting Agency

Resulting Lab	Address	City	State	Zip Code
OHSU RADIOLOGY VOICE RECOGNITION				

PACS Images

Show images for X-RAY SPINE LUMBOSACRAL 2 VIEWS

Patient Release Status:

This result is not viewable by the patient.

Radiology Start/End

Exam Begun		Exam Ended	
Feb 16, 2017	**9:35 AM**	**Feb 16, 2017**	**9:48 AM**

X-RAY SPINE LUMBOSACRAL 2 VIEWS

Order: 167662079

Status: **Final result** Visible to patient: **No (Not Released)** Next appt: **None** Dx: **Chronic bilateral low back pain witho...**

Details

Reading Physician	Reading Date	Result Priority
Erik W Foss, MD	**2/16/2017**	

Narrative

```
STUDY: SPINE LUMBOSACRAL 2 VIEWS 02/16/17 09:35:58

HISTORY: Pain.

COMPARISON: None.

FINDINGS:
There is 13 degrees lumbar dextroscoliosis.  4 mm L2-3 retrolisthesis is
present. There is no fracture or focal osseous destruction.  There is
mild L2-3 and L5-S1 and mild to moderate L4-5 degenerative disk disease.
 There is lower lumbar facet degeneration.  The soft tissues are normal.

IMPRESSION:
```

4 mm L2-3 retrolisthesis. Minimal lumbar dextroscoliosis.

Mild/moderate L4-5 and mild L2-3 and L5-S1 degenerative disk disease.

Lower lumbar facet degeneration.

I have personally reviewed the images and, if necessary, edited the report. I agree with the report as now presented.

Specimen Collected: **02/16/17 9:57 AM** Last Resulted: **02/16/17 9:58 AM**

Signed by

Signed	Prelimed	Date/Time
FOSS, ERIK W		2/16/2017 09:58

Result Information

Status	Provider Status
Final result (Exam End: 2/16/2017 9:48 AM)	**Open**

External Results Report

Open External Results Report

Order [RAD01120] (Order #: 167662079) **X-RAY SPINE LUMBOSACRAL 2 VIEWS Qty: 1**

Order Information

Date and Time	Department	Released By	Authorizing
2/16/2017 9:20 AM	Radiology/Imaging Lab at CHH	Wendy Olmstead	Yun Long Ong, NP

Release Date/Time	Start Date/Time	End Date/Time
02/16/17 09:20 AM	02/16/17 09:20 AM	2/16/2017

PACS Images

Show images for X-RAY SPINE LUMBOSACRAL 2 VIEWS

Order Details

Frequency	Duration	Priority	Order Class
None	1 occurrence	Routine	Normal

Process Instructions

To schedule your appointment, please call (503) 418-0990.

Order Providers

Authorizing Provider	Encounter Provider	Billing Provider
Yun Long Ong, NP	RAD OP CHGEN1	Erik W Foss, MD

Specialty of Authorizing
Nurse Practitioner Acute Care
Pain Medicine

Collection Information

Specimen #	Collection Date and Time
E28480	2/16/2017 0957

Protocol Summary

This study doesn't have any protocol information

Original Order

Ordered On	Ordered By
2/16/2017 0913	Yun Long Ong, NP

Associated Diagnoses

Diagnosis Description	ICD9	ICD10
Chronic bilateral low back pain without sciatica	724.2, 338.29	M54.5, G89.29

Comments

BP on (02/16/2017) 137/93, Ht on (02/16/2017) 1.676 m (5' 6"), Wt on (02/16/2017) 61.2 kg (135 lb)

Order Questions

Question	Answer	Comment
Reason/Referral Dx	**Low back pain (worsened since 2014)**	
Is this paid for by an IRB-approved research study?	**No**	

Appointments for this Order

2/16/2017 10:10 AM - 15 min	RAD OP CHGEN1 (Resource)	Rad General Chh

Encounter

View Encounter

Encounter Specific Audit Trail

View Encounter Specific Audit Trail

Order Tracking

X-RAY SPINE LUMBOSACRAL 2 VIEWS (Order #167662079) on 2/16/17

Display Printed Requisition

X-RAY SPINE LUMBOSACRAL 2 VIEWS (Order #167662079) on 2/16/17

Results

X-RAY SPINE CERVICAL 2 VIEWS (Order 167662077)

Patient Information

Patient Name	Sex	DOB
Butler, Janell	**Female**	**7/22/1974**

Collection Information

Specimen #	Collection Date and Time
E28479	**2/16/2017 0958**

Resulting Agency

Resulting Lab	Address	City	State	Zip Code
OHSU RADIOLOGY VOICE RECOGNITION				

PACS Images

Show images for X-RAY SPINE CERVICAL 2 VIEWS

Patient Release Status:

This result is not viewable by the patient.

Radiology Start/End

Exam Begun	Exam Ended
Feb 16, 2017 9:35 AM	**Feb 16, 2017 9:48 AM**

X-RAY SPINE CERVICAL 2 VIEWS

Order: 167662077

Status: **Final result** Visible to patient: **No (Not Released)** Next appt: **None** Dx: **Neck pain on left side**

Details

Reading Physician	Reading Date	Result Priority
Bryan M Wolf, MD	**2/16/2017**	

Narrative

```
STUDY: SPINE CERVICAL 2 VIEWS 02/16/17 09:35:51

HISTORY: Chronic neck pain.

COMPARISON:  February 16, 2027

FINDINGS:

 There is mild reversal of the cervical lordosis at C4-C5. There are mild
2 mm C3-C5 anterolistheses. Mild C5-C7 disc space narrowing and endplate
spurring are noted. Mid cervical facet arthropathy is observed. The soft
tissues are normal.

IMPRESSION:
```

Mild grade 1 and C3-C5 anterolisthesis.

Mild C5-C7 degenerative disc disease end midcervical facet arthropathy.

I have personally reviewed the images and, if necessary, edited the report. I agree with the report as now presented.

Specimen Collected: 02/16/17 9:58 AM | Last Resulted: 02/16/17 10:52 AM

Signed by

Signed	Prelimed	Date/Time
WOLF, BRYAN M		2/16/2017 10:52

Result Information

Status	Provider Status
Final result (Exam End: 2/16/2017 9:48 AM)	Open

External Results Report

Open External Results Report

Order **X-RAY SPINE CERVICAL 2 VIEWS [RAD01116]**
(Order #: 167662077) Qty: 1

Order Information

Date and Time	Department	Released By	Authorizing
2/16/2017 9:20 AM	Radiology/Imaging Lab at CHH	Wendy Olmstead	Yun Long Ong, NP

Release Date/Time	Start Date/Time	End Date/Time
02/16/17 09:20 AM	02/16/17 09:20 AM	2/16/2017

PACS Images

Show images for X-RAY SPINE CERVICAL 2 VIEWS

Order Details

Frequency	Duration	Priority	Order Class
None	1 occurrence	Routine	Normal

Process Instructions

To schedule your appointment, please call (503) 418-0990.

Order Providers

Authorizing Provider	Encounter Provider	Billing Provider

Yun Long Ong, NP	RAD OP CHGEN1	Bryan M Wolf, MD

Specialty of Authorizing
Nurse Practitioner Acute Care
Pain Medicine

Collection Information

Specimen #	Collection Date and Time
E28479	2/16/2017 0958

Protocol Summary

This study doesn't have any protocol information

Original Order

Ordered On	Ordered By
2/16/2017 0913	Yun Long Ong, NP

Associated Diagnoses

Diagnosis Description	ICD9	ICD10
Neck pain on left side	723.1	M54.2

Comments

BP on (02/16/2017) 137/93, Ht on (02/16/2017) 1.676 m (5' 6"), Wt on (02/16/2017) 61.2 kg (135 lb)

Order Questions

Question	Answer	Comment
Reason/Referral Dx	**Neck pain (chronic since 2014)**	
Is this paid for by an IRB-approved research study?	**No**	

Appointments for this Order

2/16/2017 9:50 AM - 20 min	RAD OP CHGEN1 (Resource)	Rad General Chh

Encounter

View Encounter

Encounter Specific Audit Trail

View Encounter Specific Audit Trail

Order Tracking

X-RAY SPINE CERVICAL 2 VIEWS (Order #167662077) on 2/16/17

Display Printed Requisition

X-RAY SPINE CERVICAL 2 VIEWS (Order #167662077) on 2/16/17

Results

X-RAY SHOULDER 2 VIEWS LEFT (Order 167662075)

Patient Information

Patient Name	Sex	DOB
Butler, Janell	Female	7/22/1974

Collection Information

Specimen #	Collection Date and Time
E28478	2/16/2017 0948

Resulting Agency

Resulting Lab	Address	City	State	Zip Code
OHSU RADIOLOGY VOICE RECOGNITION				

PACS Images

Show images for X-RAY SHOULDER 2 VIEWS LEFT

Patient Release Status:

This result is not viewable by the patient.

Radiology Start/End

Exam Begun	Exam Ended
Feb 16, 2017 9:30 AM	Feb 16, 2017 9:48 AM

X-RAY SHOULDER 2 VIEWS LEFT

Order: 167662075

Status: **Final result** Visible to patient: **No (Not Released)** Next appt: **None** Dx: **Left anterior shoulder pain**

Details

Reading Physician	Reading Date	Result Priority
Bryan M Wolf, MD	2/16/2017	

Narrative

STUDY: SHOULDER 2 VIEWS LEFT 02/16/17 09:30:30

HISTORY: Pain.

COMPARISON: None.

FINDINGS:

The glenohumeral joint is mildly narrowed with only trace articular spurring. There is a focal lucency in the distal, central subchondral clavicle, with poor delineation of the subchondral bone plate. The joint space does not appear significantly narrowed and there is no significant periarticular spurring. The soft tissues are normal.

IMPRESSION:

Small subchondral lucency in the distal left clavicle is favored to represent a degenerative subchondral cyst, although an erosion may be

considered in if there is clinical concern for inflammatory arthropathy.

Mild left glenohumeral joint space narrowing is favored to be degenerative.

I have personally reviewed the images and, if necessary, edited the report. I agree with the report as now presented.

Specimen Collected: **02/16/17 9:48 AM** Last Resulted: **02/16/17 9:56 AM**

Signed by

Signed	Prelimed	Date/Time
WOLF, BRYAN M		2/16/2017 09:56

Result Information

Status	Provider Status
Final result (Exam End: 2/16/2017 9:48 AM)	**Open**

External Results Report

Open External Results Report

Order (Order #: 167662075) Qty: 1 **X-RAY SHOULDER 2 VIEWS LEFT [RAD01096]**

Order Information

Date and Time	Department	Released By	Authorizing
2/16/2017 9:20 AM	Radiology/Imaging Lab at CHH	Wendy Olmstead	Yun Long Ong, NP

Release Date/Time	Start Date/Time	End Date/Time
02/16/17 09:20 AM	02/16/17 09:20 AM	2/16/2017

PACS Images

Show images for X-RAY SHOULDER 2 VIEWS LEFT

Order Details

Frequency	Duration	Priority	Order Class
None	1 occurrence	Routine	Normal

Process Instructions

To schedule your appointment, please call (503) 418-0990.

Order Providers

Authorizing Provider	Encounter Provider	Billing Provider
Yun Long Ong, NP	RAD OP CHGEN1	Bryan M Wolf, MD

Specialty of Authorizing
Nurse Practitioner Acute Care
Pain Medicine

Collection Information

Specimen #	Collection Date and Time
E28478	2/16/2017 0948

Protocol Summary

This study doesn't have any protocol information

Original Order

Ordered On	Ordered By
2/16/2017 0913	Yun Long Ong, NP

Associated Diagnoses

Diagnosis Description	ICD9	ICD10
Left anterior shoulder pain	719.41	M25.512

Comments

BP on (02/16/2017) 137/93, Ht on (02/16/2017) 1.676 m (5' 6"), Wt on (02/16/2017) 61.2 kg (135 lb)

Order Questions

Question	Answer	Comment
Reason/Referral Dx	**Left shoulder (3 years chronic pain)**	
Is this paid for by an IRB-approved research study?	**No**	

Appointments for this Order

2/16/2017 9:35 AM - 15 min	RAD OP CHGEN1 (Resource)	Rad General Chh

Encounter

View Encounter

Encounter Specific Audit Trail

View Encounter Specific Audit Trail

Order Tracking

X-RAY SHOULDER 2 VIEWS LEFT (Order #167662075) on 2/16/17

Display Printed Requisition

X-RAY SHOULDER 2 VIEWS LEFT (Order #167662075) on 2/16/17

OREGON HEALTH & SCIENCE UNIVERSITY

Summary of Your Visit

Visit Information

Date & Time	Provider	Department	Dept. Phone	Encounter #
2/16/2017 9:05 AM	Yun Long Ong, NP	Pain Center at CHH 15th Floor	503-494-7246	1050552090

Reason for Visit

Back pain
Knee pain
Hip pain

Patient Instructions

*Please continue with your Physical therapy for your left shoulder, left hip and back.

*Encourage smoking cessation.

*Please proceed to the 3rd floor to complete imaging of your left shoulder, neck and low back.

Vitals

Most recent update: 2/16/2017 8:42 AM by Anabel Lara, MA

BP	Pulse	Resp	Ht	Wt	SpO2
(!) 137/93 (BP Location: Left upper arm, Patient Position: Sitting)	77	16	1.676 m (5' 6")	61.2 kg (135 lb)	100%

BMI
21.79 kg/m2

Vitals History

Problems That Were Updated This Visit

Chronic bilateral low back pain without sciatica
Left anterior shoulder pain
Neck pain on left side

Allergies

No Known Allergies

Upcoming Administrations

None

Orders

Future Labs/Procedures	To Be Done	Expires
X-RAY SHOULDER 2 VIEWS LEFT	2/16/2017	3/16/2018
To schedule your appointment, please call (503) 418-0990.		
X-RAY SPINE CERVICAL 2 VIEWS	2/16/2017	3/16/2018
To schedule your appointment, please call (503) 418-0990.		
X-RAY SPINE LUMBOSACRAL 2 VIEWS	2/16/2017	3/16/2018

Orders (continued)

Future Labs/Procedures	To Be Done	Expires

To schedule your appointment, please call (503) 418-0990.

Immunizations

Immunizations from registries, colored red below, may not be present in the patient's chart and need to be manually reconciled.

DT-Peds	**9/28/2005**
Flu trivalent injectable	**11/8/2014 , 11/14/2011**
Flu trivalent injectable pfree	**11/26/2013**
Flu whole virus	**10/19/2007**
Influenza, split	**9/18/2009 , 11/20/2006**
Influenza-H1N1-09, nasal	**12/21/2009**
Tdap	**11/20/2006**

A Message from OHSU

As part of OHSU's commitment to providing excellent patient care and customer service, you may receive a survey in the mail from a third party, Press Ganey, asking you to evaluate your office visit with the clinician listed at the top of the survey.

Our goal is to provide you with outstanding service and high quality medical care. In order to do this we need your help in understanding our strengths as well as areas for improvement. We encourage you to take a few moments to complete this survey and return it. Your honest feedback is valuable to us in our efforts to improve.

Thank you for choosing OHSU. We look forward to partnering with you in your health care.

Current Outpatient Medication List
Oregon Health & Science University
Portland, OR 97239

This is your current medication list. Keep this with you and show it to your community pharmacist(s) and physician(s) at each visit.

Patient: Janell Butler
DOB: 7/22/1974
Physician: YUN LONG ONG, NP
Allergies: Review of patient's allergies indicates no known allergies.

Outpatient Current Medications (Including Meds Taken as Needed) as of 2/16/2017

	Dosage
amitriptyline 25 mg oral tablet	Take 1 tablet by mouth once daily at bedtime. Take one tablet by mouth once daily at bedtime. In two weeks, may increase to two tablets by mouth once daily at bedtime if tolerated.
busPIRone 5 mg oral tablet	Take 5 mg by mouth three times daily.
HYDROcodone-acetaminophen 5-325 mg oral tablet	Take 1 tablet by mouth every four hours as needed.
ibuprofen 800 mg oral tablet	Take 800 mg by mouth every six hours as needed.
lisinopril-hydrochlorothiazide 20-25 mg oral tablet	Take 1 tablet by mouth once daily.
polyethylene glycol 17 gram/dose oral powder	Mix 17 g in liquid and drink once daily.